UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

S.F., as Parent and Natural Guardian of S.E.F., an Infant, Plaintiff v. ARCHER-DANIELS-MIDLAND COMPANY, CARGILL, INC., INGREDION INCORPORATED, PENFORD PRODUCTS CO., TATE & LYLE INGREDIENTS AMERICAS, LLC, and ROQUETTE AMERICA, INC., Defendants.	)	Case No. 13-cv-00634 Chief Judge William M. Skretny

REPLY MEMORANDUM OF LAW OF ARCHER-DANIELS-MIDLAND COMPANY, CARGILL, INC., INGREDION INCORPORATED, AND TATE & LYLE INGREDIENTS AMERICAS LLC IN SUPPORT OF THEIR MOTION TO DISMISS

Dated: Buffalo, New York
November 1, 2013

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

OTHER AUTHORITIES

Plaintiff's response to Defendants' Motion to Dismiss her Complaint was essentially to abandon it. She has moved to amend the Complaint, and much of her legal memorandum is devoted to the proposed Amended Complaint. But there is only one Complaint now before the Court, and it should be dismissed. In their Opposition to the motion to amend, Defendants explain why the amendment is futile and proves the case should be dismissed with prejudice.

What little Plaintiff says in defense of the Complaint cannot save it. She argues that the Complaint sufficiently alleges that HFCS caused her diabetes because Defendants cannot establish that diabetes has any other causes. Yet diabetes has existed for thousands of years longer than HFCS. The diabetes risk factors are well known, but the Complaint ignores them.

Plaintiff does not deny that if her diabetes was caused by eating too much sugars, Defendants are not liable. And she cannot deny that the forms of HFCS most commonly used in foods and beverages do not contain any more fructose than sugar. So her Response focuses on much less common sweeteners with higher concentrations of fructose. But the Complaint never alleges she ate any foods containing these other sweeteners, a critical omission.

Plaintiff likewise fails to respond meaningfully to Defendants' arguments that her claims are preempted by federal law. Again here, Plaintiff turns her focus to sweeteners other than the common formulations of HFCS, but that cannot be a plausible basis for this lawsuit. This Court should dismiss the Complaint with prejudice.

STANDARD OF REVIEW

Plaintiff claims to be exempt from the pleading standards of *Twombly* and *Iqbal* because "this is a strict products liability and failure to warn case, not a Sherman Antitrust/ Conspiracy action (*Bell Atlantic Corp. v. Twombly* ...) that requires highly specific pleadings." (Resp. at 1-2, 5.) That is wrong. *Twombly* and *Iqbal* (which is not an antitrust case) both interpreted Rule 8, which applies to all complaints. Their standards plainly apply to product liability claims.

Desabio v. Howmedica, 817 F. Supp. 2d 197, 206 (W.D.N.Y. 2011) (Skretny, C.J.).

In what the Response (at 2) describes as an "exercise of caution," Plaintiff also moves for leave to amend the Complaint. But the only pleading now before the Court is the Complaint, and it should be dismissed. Defendants' Opposition to Plaintiff's motion explains why the proposed amendment is futile and should be rejected. *Semper v. New York Methodist Hosp.*, 786 F. Supp. 2d 566, 573, 582 (E.D.N.Y. 2011) (ruling separately on motions to dismiss and amend).

ARGUMENT

I. The Complaint fails to state a plausible claim.

A. Causation

In their Motion (at 5-9 & n.2), Defendants explained that the Supreme Court's decisions in *Twombly* and *Dura* require a complaint to contain factual allegations plausibly showing that the defendant's conduct, rather than other causes, is responsible for the plaintiff's injury. As the court explained in *Pelman v. McDonald's*, 237 F. Supp. 2d 512, 537 n.27 (S.D.N.Y. 2003): "it is impossible as a matter of law to blame one restaurant chain—even one responsible for up to seven meals a week of a plaintiff—when the plaintiffs were eating other foods (perhaps from other restaurants), were engaged in a lifestyle that may or may not have included an appropriate physical regimen, and when their weights were potentially influenced by a host of other factors, such as heredity, the environment, society, etc. Plaintiffs must get over this hurdle to survive a motion to dismiss..." The Complaint contains no such allegations: how much HFCS Plaintiff ate, how much of other sweeteners (such as sugar or honey) Plaintiff ate, what other foods Plaintiff ate, Plaintiff's weight and levels of physical activity over time, Plaintiff's genetics, Plaintiff's family background and diabetes history, or any other factors known to present risks for diabetes.

Instead, Plaintiff makes two insufficient arguments. The first is that Defendants have not shown that there are any other causes of diabetes. (Resp. at 5-6.) But of course there are. HFCS

was first available in the 1960s (Compl. ¶ 17); diabetes has existed for millennia.

To identify the risk factors for diabetes, Defendants cited representative publications of the National Diabetes Information Clearinghouse and the National Diabetes Education Program, both part of the U.S. Department of Health and Human Services, as well as the *Pelman* decision. (Mot. at 7-8 & n.3.)[1] It could not be any clearer that many factors play a role in diabetes.

Plaintiff inadvertently disproves her own argument by asserting that "correlation does not equal causation." (Resp. at 6.) That is Defendants' point. Plaintiff may have eaten some unidentified amount of HFCS in unidentified foods at unidentified times, and she may now be diabetic, but that does not plausibly show, as *Twombly* requires, that one caused the other. Millions of people eat HFCS every year without becoming diabetic.

Plaintiff's second argument is that instead of requiring her to "disprove all potential causes of her disease," New York law requires her to prove only that HFCS is "a substantial factor in bringing about" her diabetes, though it "cannot be slight or trivial." (Resp. at 6.) In other words, New York law recognizes that injuries may have more than one cause — as diabetes plainly does — and that some causes are "substantial" and others are "slight or trivial." The issue now is whether the Complaint plausibly alleges that HFCS was a factor at all, much less a substantial one. For the reasons explained above and in Defendants' Motion, it does not.

B. Connection to Defendants

To Defendants' argument that the Complaint does not connect any of them to the HFCS in the foods she ate and therefore (under her theory) to her diabetes, Plaintiff responds that she is asserting market share liability under *Hymowitz v. Eli Lilly*, 73 N.Y.2d 487 (1989). The Complaint neither mentions market share liability nor plausibly pleads it.

[1] Defendants also could have cited the American Diabetes Association, http://www.diabetes.org/diabetes-basics/prevention/risk-factors/; http://www.diabetes.org/diabetes-basics/genetics-of-diabetes.html, or numerous other sources.

In *Hymowitz*, a case about an unusual cancer caused by the drug DES, the court recognized that "identification of the exact defendant whose product injured the plaintiff is, of course, generally required..." *Id*. at 504. But given that DES was made by "a great number of possible wrongdoers," and given that pharmacies filled prescriptions with whatever pills they had on hand, it was "impossible" for any plaintiff to identify the relevant DES manufacturer(s). *Id*. at 502-06. The Court "stress[ed] ... that the DES situation is a singular case," in part because the New York legislature had passed a special law reviving old DES cases. *Id*. at 508.

"Outside the DES context, market share liability has been sparingly adopted." *In re New York Silicone Breast Implant Litig.*, 631 N.Y.S.2d 491, 493 (N.Y. Sup. 1995), *aff'd* 234 A.D.2d 28 (N.Y. App. Div.). New York courts have "refused to extend the market share theory beyond cases involving DES," *Brenner v. American Cyanamid*, 263 A.D.2d 165, 171 (N.Y. App. Div. 1999), including cases about silicone implants, cigarettes, guns, and lead. *In re New York Silicone Breast Implant Litig.*, 631 N.Y.S.2d at 494; *DaSilva v. American Tobacco Co.*, 175 Misc.2d 424, 427 (N.Y. Sup. 1997); *Hamilton v. Beretta USA*, 96 N.Y.2d 222, 240-41 (2001).

The situation here is very different from *Hymowitz*. The Complaint does not allege it would be impossible to identify the maker of HFCS in any food — the Complaint does not even identify any food. And the legislature has not taken special action to favor HFCS lawsuits. *Brenner*, 263 A.D.2d at 173. On the contrary, the legislature has consistently declined to pass a proposed anti-HFCS bill. N.Y. Assembly Bill 2865, 2013 Legislature.

Courts asked to apply market share liability consider six factors, none of them supporting it here. From section 15(c) of the Restatement (Third) of Torts, Product Liability, those factors, and the reason they do not apply here, are:

> 1. *The generic nature of the product.* Although HFCS is a commodity, the products that Plaintiff bought and ate are not. *Brenner*, 263 A.D.2d at 172 (in a case against makers of an ingredient for paint, the relevant product was the paint: "the finished product that was used by consumers here ... was not fungible"). In *Hymowitz*, the product was DES itself,

made by every defendant. But the finished products here are identifiable foods with name brands, as the affidavit of Plaintiff's mother shows. *DaSilva*, 175 Misc.2d at 427 (rejecting market share liability because plaintiffs could identify brands).

2. *The long latency period of the harm.* The Complaint alleges nothing about when Plaintiff ate specific foods containing HFCS.

3. *The inability of plaintiffs to discover which defendant's conduct caused plaintiff's harm, even after exhaustive discovery.* The Complaint alleges nothing to show this.

4. *The clarity of the causal connection between the defective product and the harm suffered by plaintiffs.* The causal connection here is nonexistent.

5. *The absence of other factors that could have materially contributed to the harm.* In *Hymowitz*, the plaintiffs all developed the same uncommon cancer — a "signature injury." *Brenner*, 263 A.D.2d at 172. Diabetes is not a signature injury of HFCS.

6. *The availability of sufficient market share data.* The Complaint alleges nothing about market share. And because HFCS is only one of many sources of fructose — the others include sugar and honey and products containing them, as well as many different kinds of fruits and vegetables — there has been no showing that the fructose market can accurately be divided. *Id*. at 171.

For all of these reasons, the Complaint does not plausibly allege market share liability.

C. Overconsumption of Sugars

Overconsuming foods is not a basis for liability: "any food ... necessarily involves some risk of harm, if only from overconsumption. ... Good butter is not unreasonably dangerous merely because, if such be the case, it deposits cholesterol in the arteries and leads to heart attacks." RESTATEMENT (SECOND) OF TORTS § 402A cmt. i. The Restatement singles out sugars as one such food. Plaintiff does not dispute the legal principle.

Her only hope, then, is to show that the fructose in HFCS presented some unknown danger beyond the fructose in sugar and other sugars. Yet she does not deny that it is the same fructose, or that the forms of HFCS commonly used in foods and beverages in the United States[2] contain markedly less fructose (HFCS 42) or roughly the same amount of fructose (HFCS 55) as sugar and honey. Thus, even assuming *arguendo* that fructose is harmful when overeaten, HFCS is sugar's nutritional equivalent, and Defendants are not liable.

[2] *HFCS Q&A*, attached as Appendix B to Defendants' Motion.

Instead, Plaintiff accuses Defendants of having asserted differences between HFCS and sugar in a brief and expert reports from a different case in 1997. The charge lacks merit. The 1997 case was an anti-dumping dispute under the Mexican Foreign Trade Act. The brief and expert reports discussed things such as physical differences between HFCS (a liquid) and sugar (a solid). None of them contradicted the only important point here: the fructose in HFCS and in sugar has the exact same effect when digested—they are nutritional equals.

Plaintiff's response focuses attention on the comparatively rare[3] products, HFCS 90 (90 percent) and Crystalline Fructose (roughly 100 percent), which have a higher fructose-to-glucose ratio than HFCS 42 and 55, sugar, and honey. Plaintiff also mentions something she calls "HFCS 65," which is unknown to Defendants. It does not exist.

The Complaint does not mention "HFCS 65" or Crystalline Fructose, and it does not allege that Plaintiff ever ate them or HFCS 90. Plaintiff even admits that she does not know "the extent or scope of use" of those ingredients, "whether it is pervasive or inconsequential." (Resp. at 17.)[4] For that reason alone, her new arguments fail to help her allege a plausible claim.

In addition, Plaintiff's focus on concentrations of fructose is unhelpful. Higher concentrations can be found elsewhere than HFCS. Take an apple. A 100 gram apple contains 5.9 grams of fructose, 2.4 grams of glucose, and 2.1 grams of sucrose (which is half fructose and half glucose).[5] The fructose-to-glucose ratio of an apple, then, is 2-1. That is much higher than

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[3] As the document cited in Amended Complaint ¶ 65 explains, "HFCS 90 has only been employed for very limited uses in food products, and FDA has been aware of these limited uses for decades. ... [C]onsumer exposure to fructose through HFCS 90 is minimal..." Letter from J. Patrick Mohan, Interim President, Corn Refiners Association, to FDA (January 30, 2013) (Docket No. FDA-2012-P-0904), at 8.

[4] Her earlier statement that HFCS 65 and 90 and Crystalline Fructose are used in a long list of foods is supported by a citation to a single document on the corn.org website. (Resp. at 8 n.5.) The document does not say anything about uses of those ingredients.

[5] The apple and dried fig numbers in the text come from the U.S. Department of Agriculture's National Nutrient Database for Standard Reference, http://ndb.nal.usda.gov/.

the fructose concentration of HFCS 42 or 55.

To Plaintiff, focused only on fructose consumption, the ratio alone does not matter. What matters is the total amount of fructose. Focusing on concentrations would lead one to think that eating 100 grams of apple is better than eating 100 grams of dried fig, because the dried fig has a fructose-to-glucose ratio of just under 1 (slightly less fructose than glucose). Yet the dried figs contain over 3 times as much total fructose, 22.9 grams compared to 6.95 grams in the apple. Fructose concentration, in other words, has little to do with how much fructose is in any food. ***And the amount of fructose that is included in a food product is determined by the food's maker, not by Defendants.*** *Brenner*, 263 A.D.2d at 172. Just as wheat flour companies do not control how much wheat goes into some other company's cookie, neither do Defendants.

Allowing this case to go forward based only on higher fructose formulations would make proving causation completely impossible. Even if, contrary to reality, Plaintiff could prove that HFCS (not all other sweeteners, foods, and all other risk factors for diabetes) made her diabetic, she could never show that only the less common sweeteners HFCS 90 and Crystalline Fructose, rather than the far more common sweeteners HFCS 42 and 55, were the cause.

D. Food Package Labels

Defendants cannot put warnings on the labels of other companies' products, so they cannot be held liable for failing to do so. Plaintiff nonetheless asserts that even if requiring such warnings is "[i]mplausible," still Defendants are liable. (Resp. at 19.) It will not do to pretend that "the law is an ass—an idiot" by requiring the impossible. Charles Dickens, OLIVER TWIST 400 (Vintage ed. 2012) (1837). The failure to warn claim should be dismissed.

II. Federal law preempts Plaintiff's causes of action.

As explained below, federal law preempts Plaintiff's causes of action about the forms of HFCS most commonly used in food and beverages in the United States, HFCS 42 and 55.

A. Federal law mandates the design of HFCS.

The Complaint asserts that HFCS is defectively designed, but federal law mandates that design. HFCS 42 and 55 are required to have "approximately 42 or 55 percent fructose," respectively, 21 C.F.R. § 184.1866(a), and it is that fructose which Plaintiff claims makes HFCS defective. Defendants cannot be liable under state law for following federal requirements.

Plaintiff offers two counterarguments. The first is that the Food Chemicals Codex requires "[n]ot less than" those percentages, so Defendants are free to use as much fructose as they like. Not so. FDA's regulation requires "approximately 42 or 55 percent fructose," subject to the variations of "current good manufacturing practice." *Id.* §§ 184.1866(a), (c). The Codex sets a floor on the level of fructose, to ensure that the minimum required amount is included. The Codex does not (and cannot) authorize ignoring the regulation and its requirement that the amount be approximately as specified; it simply acknowledges the possibility, because of manufacturing conditions, that the amount will not be precisely 42 or 55 percent.

Defendants cited *Mutual Pharm. v. Bartlett*, 133 S. Ct. 2466 (2013), as an example of a case in which the design of a product (there, a drug) was mandated by federal law, preempting a design defect claim. (Mot. at 17.) Plaintiff's second argument is that *Bartlett* is somehow distinguishable because drugs go through a lengthy approval process. (Resp. at 11-12.) But the approval process has nothing to do with preemption based on the existence of federal design requirements, which are likewise present here. In any event, HFCS 42 and 55 went through their own 8-year approval process to be affirmed as GRAS, as described below.

Finally, Plaintiff faults Defendants for not discussing *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), where the Supreme Court supposedly held "that federal law does not preempt strict product liability or failure to warn claims against food additive companies." (Resp. at 9.) *Wyeth* is a decision about drugs, not food additives. And it illuminates nothing here. In *Wyeth*, the

defendant argued that FDA regulations barred and therefore preempted a requested warning. *Id*. at 1196-97. The Supreme Court held the regulations were no bar, so the claim was not preempted. *Id*. at 1197-98. *Wyeth* gives no guidance for this case.

B. Federal law affirms that HFCS is safe.

The Complaint asserts that HFCS is "a toxin" under New York law, but federal law holds that HFCS 42 and 55 are Generally Recognized As Safe (GRAS) and may be used in food without limitation. A food ingredient cannot be GRAS under federal law and toxic under state law. As another court recently held, "provid[ing] pages of information on the health risks associated with" a food ingredient "in the hopes of classifying [it] as 'poisonous or deleterious'" cannot overcome a federal GRAS designation. *Simpson v. California Pizza Kitchen*, 2013 WL 571849, at *6 (S.D. Cal.). "By definition, something that is 'generally regarded as safe' cannot at the same time be 'not safe for human consumption.'" *Id.* at *9 (granting motion to dismiss). Plaintiff's Response does not address the irreconcilable conflict between federal law and (her view of) New York law on this point.

Instead, Plaintiff criticizes the FDA's decision. Plaintiff asserts the GRAS designation (a) was granted back in 1983 and is therefore based on old science, (b) may have been based on "ethereal" documents submitted by Defendants to the FDA 30 years ago, (c) is useless because it came before the 1994 discovery of the hormone leptin, and (d) should be ignored because today the FDA uses "voluntary notification" for GRAS status for food additives. (Resp. at 12-15.)

All of these points are incorrect. In 1996, the FDA concluded its own 8-year review of HFCS and affirmed it is GRAS. 21 C.F.R. §§ 184.1(a), 184.1866; 61 Fed. Reg. 43,447-01 at 43,447. This was two years after the discovery of leptin (*1994*), it was not based on science from *1983*, and it did not involve the current voluntary notification process for GRAS status, which Plaintiff concedes began in *1997*. (Resp. at 14.) The FDA based its affirmation not on 30-year-

old secret documents, but on "the views of experts qualified by scientific training and experience to evaluate the safety of substances directly ... added to food." 21 C.F.R. § 170.30(a). Those experts evaluated the "probable consumption of the substance," the "cumulative effect of the substance in the diet," and "[s]afety factors." *Id*. § 170.3(i)(1), (2), (3). The FDA considered (1) petitions about HFCS, (2) reports by a GRAS committee, (3) a report by the FDA's Sugars Task Force, and (4) public comments. After having "fully evaluated" all of these materials — and after rejecting assertions that HFCS plays a special role in diabetes — the FDA affirmed that HFCS is GRAS. 61 Fed. Reg. 43,447-01 at 43,447. Today, the FDA is still "not aware of any evidence" that HFCS is any different in safety than sugar and honey. *HFCS: Q&A.*

C. The entire Complaint should be dismissed.

Although only claims based on HFCS 42 and 55 are preempted, the entire Complaint should be dismissed. It never mentions the non-existent product "HFCS 65" or Crystalline Fructose, and it never alleges Plaintiff ate them or HFCS 90. Plaintiff could never prove that she became diabetic only from HFCS 90 and Crystalline Fructose, to the exclusion of HFCS 42 and 55 and all other sweeteners, all other foods, and all other risk factors. There is no reason to prolong a case that is doomed to failure and that was so implausibly alleged from the beginning.

III. The Complaint should be dismissed with prejudice.

Plaintiff's proposed Amended Complaint proves that amending would be futile, as explained in Defendants' Opposition, so the dismissal of the case should be with prejudice.

Dated: November 1, 2013 Respectfully submitted

/s/ Kevin M. Hogan
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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

S.F. as Parent and Natural Guardian of S.E.F., an Infant,	)	
Plaintiff	)	Civil Action No. 1:13-CV-634
v.	)	
ARCHER-DANIELS-MIDLAND COMPANY, CARGILL, INC., INGREDION INC., PENFORD PRODUCTS CO., TATE & LYLE INGREDIENTS AMERICAS, LLC AND ROQUETTE AMERICA, INC.,	)	
Defendants.	)	

CERTIFICATE OF SERVICE

I, Kevin M. Hogan, an attorney, hereby certify that on November 1, 2013, I caused to be filed electronically the foregoing REPLY IN SUPPORT OF MOTION TO DISMISS with the Clerk of the Court using its CM/ECF system, which will send an electronic copy of the foregoing to counsel of record and constitutes service under Federal Rule of Civil Procedure 5(b)(2)(D) pursuant to Local Rule 5.1 of the Western District of New York.

/s/ Kevin M. Hogan